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10/539,082	12/16/2005	James M Swanson	51710/CAB/R2682	9216
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EXAMINER				
GOLDBERG, JEANINE ANNE				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,082

Applicant(s)

SWANSON ET AL.

Examiner

JEANINE A. GOLDBERG

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO-893)
Paper No(s)/Mail Date 2/08; 7/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the papers filed February 19, 2008. Currently, claims 1-14 are pending. Claims 11-14 have been withdrawn as drawn to non-elected subject matter.

Election/Restrictions

2. Applicant's election without traverse of Group 1, Claims 1-10 in the paper filed February 19, 2008 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Priority

3. This application is a 371 of PCT/US03/41409, filed December 29, 2003 and claims priority to 60/439,903, filed December 26, 2002.

It is noted that the first line of the specification which was filed on February 19, 2008 contains a specific reference to the priority documents, but does not contain the date on which they were filed.

Drawings

4. The drawings are acceptable.

Specification

5. The title of the invention is not descriptive of the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

6. Claims 1 and 6 are directed to an allele of DRDR. The other claims appear to be directed to DRD4. Clarification is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claims are directed to a reagent comprising a polynucleotide "corresponding to" a polymorphism in linkage disequilibrium with an allele of DRDR associated with individuals exhibiting ADHD. The claims are not directed to an isolated DNA molecule such that the claims would be directed to statutory subject matter. This rejection may be easily overcome by amending the claims to recite an "isolated polynucleotide" such that it is clear that the "hand of man" is required and the product is nonnaturally occurring.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-10 are directed to "corresponding to" a polymorphism in LD with an allele. It is unclear what is meant by corresponding to. Corresponding to is not a generally accepted term in the art for polynucleotides. It is unclear whether the polynucleotide must merely contain a polymorphism, i.e. an A; whether the polynucleotide must be in some sort of context for the polynucleotide DRD4 or whether there is another meaning for corresponds to. It is unclear what degree of correspondence is required to meet the limitations of the instant claims. For example, primers which amplify the entire gene correspond to the DRD4 gene, but it is unclear whether they also correspond to a polymorphism in LD with an allele of DRD4. Clarification is required to determine the metes and bounds of the claimed invention.

B) Claims 1-10 are directed to an allele of DRDR associated with individuals exhibiting ADHD. A search of the art did not indicate any genes DRDR. The art teaches DRD1, DRD5, and DRD4 genes, for example. All of the claims appear to be directed to DRD4 gene, thus the examiner presumes this was a typographical error. Correction is required.

C) Claims 2 and 7 are directed to "closely linked". The term "closely" in claims 2 and 7 are a relative term which renders the claim indefinite. The term "closely" is not defined by the claim, the specification does not provide a standard for ascertaining the

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requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Ding et al. (PNAS, Vol. 99, No. 1, pages 309-314, published on line December 26, 2001).

It is noted that the authorship of the Ding et al. reference is distinct from the inventorship of the instant application and that this rejection may be overcome by the filing of a 132 Katz-type declaration.

Ding teaches evidence of positive selection acting at the human dopamine receptor DR gene locus. Ding teaches strong linkage disequilibrium was found between the 7R allele and surrounding DRD4 polymorphisms. Ding teaches reagents comprising polynucleotides for the exon 1 polymorphisms and exon 3 VNTR. These primer pairs are polynucleotides which correspond to a polymorphism in LD with an allele of DRD4 (limitations of Claim 1, 6). Ding teaches that promoter region, exon 1 and intron 3 polymorphisms are indicated in strong linkage with the DRD4 7R allele (limitations of Claim 2, 3, 7, 8). The polymorphisms of exon 1 are within 50kB or the 7R

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allele within exon 3 (limitations of Claims 4, 5, 9, 10). Thus, Ding teaches all of the limitations of the instant claims.

10. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fodor (US Publication 2001/0053519, December 20, 2001).

It is noted that the promoter region, exon 1 and intron 3 polymorphisms are inherently in strong linkage with the DRD4 7R allele.

Fodor teaches analysis using a 10-mer array (Example 2, col. 22). Figures 2-5 show results from the hybridization of a sample of DNA to an array containing all possible 10-mers which was manufactured using photolithography techniques on an array. Within the array there are many polynucleotides that comprise polymorphisms in LD with DRD4 alleles. For example, Fodor inherently teaches an ASO probe of 10 nucleotides that corresponds to the intron 3 polymorphisms which are inherently in LD with the DRD4 7R allele. Therefore, Fodor teaches a reagent comprising a polynucleotide corresponding to a polymorphism in LD with an allele of DRD4.

11. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Okuyama et al. (Biochemical and Biophysical Research Communications, Vol. 258, pages 292-295, 1999).

Okuyama examined LD of the -521 C>T polymorphism of DRD4 with the exon 3 VNTR polymorphism and found a weak LD. Okuyama further teaches primers which amplify the -521 region of the DRD4 gene. These primers are polynucleotides that correspond to a polymorphism in LD with an allele of DRD4 (limitations of Claims 1, 6).

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Okuyama further teaches PCR-restriction fragments which comprise the polymorphic allele which is in LD with the DRD4 7R allele. The DRD4 gene is less than 4,000, thus the promoter polymorphism is within 50kB of the 7R allele (limitations of Claims 4-5, 9-10). Therefore, Okuyama teaches a reagent comprising a polynucleotide corresponding to a polymorphism in LD with an allele of DRD4.

12. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Seaman et al. (Am J. Of Med. Genetics, Vol. 88, pages 705-709, 1999).

It is noted that the promoter region, exon 1 and intron 3 polymorphisms are inherently in strong linkage with the DRD4 7R allele.

Seaman teaches amplifying genomic DNA using an upstream and a downstream primer pair (see page 706, col. 1). These primers amplify the DRD4 gene. The gene is a polynucleotide that corresponds to a polymorphism in LD with an allele of DRD4. Thus, the primers and the amplicon are both polynucleotides within the scope of the claims. Seaman specifically illustrates the location of the 120bp tandem duplication and the other length variants in Figure 1. The DRD4 gene is less than 4,000, thus the promoter polymorphism is within 50kB of the 7R allele (limitations of Claims 4-5, 9-10). Therefore, Seaman teaches a reagent comprising a polynucleotide corresponding to a polymorphism in LD with an allele of DRD4.

13. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Seaman et al. (J. of Experimental Zoology, Vol. 288, pages 32-38, 2000).

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It is noted that the promoter region, exon 1 and intron 3 polymorphisms are inherently in strong linkage with the DRD4 7R allele.

Seaman teaches primers D4EX1F and D4EX1R that are primer for typing exon 1 12pb polymorphism. These primers correspond to the polymorphism in exon 1 which is in LD with the DRD4 7R allele. These primers are within 50kB of the 7R allele. Thus, the typing primers of Seaman anticipated the claimed invention.

Conclusion

14. No claims allowable over the art.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

**/Jeanine Goldberg/
Primary Examiner
March 28, 2008**